EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE

ELLA M. REDKEVITCH and NEIL Z. REDKEVICH,	)	
Plaintiffs,	)	
v.	)	**CASE NO. _____**
	)	**JURY DEMAND**
AMERIDOSE, LLC, MEDICAL SALES MANAGEMENT, INC., MEDICAL SALES MANAGEMENT SW, INC., GDC PROPERTIES MANAGEMENT, LLC, ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, BARRY J. CADDEN, GREGORY CONIGLIARO, LISA CONIGLIARO CADDEN, DOUGLAS CONIGLIARO, CARLA CONIGLIARO, GLENN A. CHIN, SAINT THOMAS OUTPATIENT NEUROSURGICAL CENTER, LLC, SAINT THOMAS WEST HOSPITAL formerly known as ST. THOMAS HOSPITAL, SAINT THOMAS NETWORK, SAINT THOMAS HEALTH, ASCENSION HEALTH ALLIANCE, ASCENSION HEALTH,	)	
Defendants.	)	

COMPLAINT

COME NOW the Plaintiffs Ella M. Redkevitch and Neil Z. Redkevitch, and for complaint against the above named Defendants would show as follows:

INTRODUCTION

1. In 2012, a widespread outbreak of fungal meningitis injured over 700 people in more than 20 states. At least 61 people have died.

2. The Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") identified fungus in multiple lots of the Defendants-supplied injectable steroids, specifically methylprednisolone acetate ("MPA"). The FDA and CDC concluded that the MPA, which was compounded at The New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC") facilities, was the cause of the fungal meningitis outbreak and resulting injuries and deaths. NECC's facilities located in Framingham, Massachusetts were unsterile, and were the source of fungus that contaminated vials holding Defendants' compounded medications.

3. Multiple vials of MPA compounded at NECC have been recalled, but the recall was too late for Ella M. Redkevitch, and for many others who suffered serious and/or catastrophic injuries or death.

PARTIES

4. Plaintiffs Ella M. Redkevitch and Neil Z. Redkevitch reside in Nashville, Davidson County, Tennessee.

5. Defendant Ameridose, LLC, ("Ameridose") is a Massachusetts limited liability company with a principal place of business at 205 Flanders Road, Westborough,

Massachusetts, 01581. The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

6. Defendant Medical Sales Management, Inc., ("MSM") is a Massachusetts corporation with its principal place of business at 697 Waverly Street, Framingham, Massachusetts, 01702. Douglas Conigliaro is the President and a Director of MSM, Barry Cadden is the Treasurer and a Director of MSM, and Gregory Conigliaro is the Secretary and a Director of MSM. MSM's registered agent is Gregory Conigliaro.

7. Defendant Medical Sales Management SW, Inc., ("MSMSW") is a Massachusetts corporation with its principal place of business at 697 Waverly Street, Framingham, Massachusetts, 01702. Douglas Conigliaro is the President and a Director, Barry Cadden is the Treasurer and a Director, Gregory Conigliaro is the Secretary and a Director and Lisa Conigliaro Cadden is a Director. MSMSW's registered agent is Gregory Conigliaro.

8. Defendant GDC Properties Management, LLC, ("GDC") is a Massachusetts limited liability company with its principal place of business at 701 Waverly Street, Framingham, Massachusetts, 01702. GDC's manager and registered agent is Gregory Conigliaro.

9. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma, 73104. The Chief Executive Officer and registered agent of ARL is Thomas C. Kupiec.

10. Defendant Barry J. Cadden ("Barry Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts, 02093. Barry Cadden was at all relevant times the President of New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"), which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record, as that term is defined by 247 CMR 2.00. Barry Cadden was a founder and Manager of Ameridose and was involved in Ameridose's day-to-day operations. Barry Cadden was also the Treasurer and Director of MSM and MSMSW.

11. Defendant Gregory Conigliaro ("Gregory Conigliaro") is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts, 01701. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a Manager of Ameridose and involved in Ameridose's day to day operations. Gregory Conigliaro is Secretary and Director of MSM and MSMSW.

12. Defendant Lisa Conigliaro Cadden ("Lisa Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts, 02093. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day-to-day operations of NECC.

13. Defendant Douglas Conigliaro ("Douglas Conigliaro") is an individual residing at 15 Hale Drive, Dedham, Massachusetts, 02026. Douglas Conigliaro is the President and a Director of MSM and MSMSW. Douglas Conigliaro, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM, and MSMSW.

14. Defendant Carla Conigliaro ("Carla Conigliaro") is an individual residing at 15 Hale Drive, Dedham, Massachusetts, 02026. Carla Conigliaro is a Director of NECC and the wife of Douglas Conigliaro.

15. Defendant Glenn A. Chin ("Glenn Chin") is an individual residing at 173 Mechanic Street, Canton, Massachusetts, 02021, and a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC. Glen Chin, upon information and belief, compounded drugs, including MPA, at NECC.

16. Defendant Saint Thomas Outpatient Neurosurgical Center, LLC, ("Saint Thomas Neurosurgical") is a Tennessee for-profit limited liability company. Saint Thomas Neurosurgical's principal place of business is located on the 9th floor of the Medical Plaza East office building on the Saint Thomas Hospital campus at 4230 Harding Pike in Nashville, Davidson County, Tennessee, 37205. Saint Thomas Neurosurgical's registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee, 37203.

17. Defendant Saint Thomas West Hospital is a Tennessee non-profit corporation with its principal place of business located on the Saint Thomas West Hospital campus at 4220 Harding Pike in Nashville, Davidson County, Tennessee. Saint Thomas West Hospital was formerly known as St. Thomas Hospital. Saint Thomas West Hospital's registered agent for service of process is E. Berry Holt, III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee, 37205. Hereinafter, Saint Thomas West Hospital shall be referred to as "St. Thomas Hospital."

18. Defendant Saint Thomas Network is a Tennessee non-profit corporation with its principal place of business located on the St. Thomas Hospital campus at 4220 Harding Pike in Nashville, Davidson County, Tennessee. Saint Thomas Network's registered agent for service of process is E. Berry Holt III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee, 37205.

19. Defendant Saint Thomas Network was formerly known as Saint Thomas Health Services.

20. Saint Thomas Network is a successor of Saint Thomas Health Services.

21. Saint Thomas Network, as the successor of Saint Thomas Health Services, is a manager of Defendant Saint Thomas Neurosurgical.

22. Saint Thomas Network, as the successor of Saint Thomas Health Services, is an owner and/or member of the Defendant Saint Thomas Neurosurgical.

23. Defendant Saint Thomas Health is a Tennessee non-profit corporation with its principal place of business in Nashville, Davidson County, Tennessee. Saint Thomas

Health's registered agent for service of process is E. Berry Holt III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee, 37205.

24. Defendant St. Thomas Health was formerly known as Saint Thomas Health Services.

25. Saint Thomas Health is a successor of Saint Thomas Health Services.

26. Saint Thomas Health, as the successor of Saint Thomas Health Services, is a manager of Defendant Saint Thomas Neurosurgical.

27. Saint Thomas Health, as the successor of Saint Thomas Health Services, is an owner and/or member of Defendant Saint Thomas Neurosurgical.

28. Defendants Saint Thomas Network and Saint Thomas Health are hereinafter referred to collectively as "Saint Thomas."

29. At the time of the events described herein, Defendants Saint Thomas and Howell Allen Clinic acted in concert to operate jointly the Defendant Saint Thomas Neurosurgical.

30. The Defendant Ascension Health is a Missouri non-profit corporation with its principal place of business in St. Louis, Missouri. At the time of the matters complained of herein, the Defendant Ascension Health owned, operated, managed and/or simply did business, in part, as Saint Thomas Health, and/or Saint Thomas Network, and/or Saint Thomas West Hospital, formerly known as St. Thomas Hospital. The registered agent listed with the Tennessee Secretary of State is Corporation Service Company, 2908 Poston Avenue; Nashville, TN 37203-1312. The registered agent with

the Missouri Secretary of State is Christine K. McCoy; 4600 Edmundson Road; St. Louis, Missouri 63134.

31. The Defendant Ascension Health Alliance is a non-profit corporation with a principal place of business in St. Louis, Missouri. At the time of the matters complained of herein, the Defendant Ascension Health owned, operated, managed and/or simply did business, in part, as Saint Thomas Health, and/or Saint Thomas Network, and/or Saint Thomas West Hospital, formerly known as St. Thomas Hospital. The registered agent for Ascension Health Alliance is Joseph R. Impicciche; 101 South Hanley Road, Suite 450; St. Louis, MO 63105.

32. Defendants Ascension Health and Ascension Health Alliance are hereinafter referred to collectively as "Ascension Health."

33. The individuals and entities described in paragraphs 5-15 are sometimes collectively referred to as the "NECC Related Defendants."

34. The individuals and entities described in paragraphs 16-32 are sometimes collectively referred to as the "Tennessee Defendants."

JURISDICTION AND VENUE

35. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1334(b) because each claim asserted herein is related to a case under title 11.

36. This case is related to the NECC Bankruptcy because the outcome of this lawsuit could likely have an effect on the bankruptcy estate.

37. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code: In re: New England Compounding Pharmacy, Inc., Debtor, United States Bankruptcy Court for the District of Massachusetts Case No. 12:19882 HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate.

38. NECC has express contractual indemnification obligations to, among others, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC, and MSM. Some, if not all, of the aforementioned individuals are insureds under NECC's insurance policies.

39. Multiple cases seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC's bankruptcy against each of the NECC Related Defendants.

40. On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings alleging death or injury based on contaminated MPA to the United States District Court for the District of Massachusetts. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multidistrict Litigation action styled: In re: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS. The transferred cases have been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.

41. The Bankruptcy Court for the District of Massachusetts has not established a deadline for the filing of claims against NECC's bankruptcy estate in In re: New England Compounding Pharmacy, Inc. at this time.

42. Saint Thomas Neurosurgical sent NECC written notice on October 16, 2012 that it intended to assert claims against NECC. Saint Thomas Neurosurgical and Howell Allen Clinic have represented themselves to the Bankruptcy Court for the District of Massachusetts as creditors of NECC who have a stake in NECC's bankruptcy proceeding as a result of Plaintiffs' claims and the claims of those similarly situated. Saint Thomas Neurosurgical objected to the Chapter 7 Trustee's motion to establish a deadline for the filing of claims in Case No. 12:19882 HJB. It argued that the proposed deadline could prevent it from filing an accurate and comprehensive account of their contribution and indemnity claims against NECC. On July 24, 2013, during oral arguments on another motion filed in Case No. 12:19882 HJB, Saint Thomas Neurosurgical characterized itself to the Bankruptcy Court as a creditor of NECC's bankruptcy estate possessed of indemnity and breach-of-warranty claims.

43. Whatever contribution, indemnity, and breach-of-warranty claims Saint Thomas Neurosurgical has against NECC is based on the contaminated methylprednisolone acetate purchased from NECC.

44. Upon information and belief, all of the Tennessee Defendants presently intend to seek relief from the stay in order to pursue contribution or indemnity claims against NECC a portion of the damages sought by this Complaint. In addition, or in the

alternative, all of the Tennessee Defendants presently intend to file, and will file, claims in NECC's bankruptcy proceeding seeking indemnification or contribution for all or some portion of the damages sought by this Complaint.

45. Plaintiffs will file a claim against NECC in its bankruptcy proceeding for the injuries at issue in this Complaint.

46. By Order dated May 31, 2013, Judge Saylor ruled that the New England Compounding Pharmacy, Inc., Multi District Litigation Court has subject-matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC regardless of whether NECC is named as a Defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013 Order include the Defendants described in paragraphs 5-15.

47. In addition or in the alternative to the basis for jurisdiction already asserted, this Court has subject-matter jurisdiction over all claims against the Tennessee Defendants pursuant to 28 U.S.C. § 1367 in that all such claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

48. Venue is proper and appropriate in the United States District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) in that all or a substantial part of the events and actions giving rise to the matters asserted in the Complaint occurred in Davidson County, Tennessee.

49. At all times relevant the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing, and/or selling or administering, either directly or indirectly, steroids in the State of Tennessee from which they derived significant and regular income.

50. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting individually and/or through their agents and employees have committed tortious actions and omissions in Davidson County, Tennessee, that have proximately caused the injuries that are the subject of this lawsuit.

51. The NECC Related Defendants described in paragraphs 5-15 are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

STATEMENT OF FACTS

A. RELEVANT BACKGROUND

52. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to pharmacies in many states throughout the United States, including Tennessee.

53. Upon information and belief, NECC was a privately-held company that was owned and controlled by Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro, Barry Cadden, and Lisa Cadden.

54. At least until October 2012, Barry Cadden was NECC's President. Barry Cadden also was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications, including MPA, at NECC.

55. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

56. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).

57. At the time of the matters complained of herein, Gregory Conigliaro was involved in co-managing the day-to-day operations of NECC, MSM, MSMSW, Ameridose, and GDC.

58. At the time of the matters complained of herein, Lisa Cadden and Glenn Chin were licensed pharmacists who, upon information and belief, compounded medications, including MPA, at NECC.

59. According to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, Ameridose is a "distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

60. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

61. Upon information and belief, on multiple occasions, employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC's principals.

62. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

63. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including MPA.

64. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

65. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

66. ARL holds itself out as a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry.

67. According to its Internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."

68. ARL also states on its Internet website that it follows "USP monographs/general chapters[,]" and that it has a formal Quality Assurance Program in compliance with "USP monographs/general chapters[.]"

69. Upon information and belief, ARL provided sterility testing services and information to NECC for its compounded medications, including MPA.

70. GDC, which is an acronym for "Gregory D. Conigliaro," owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

71. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

72. GDC describes one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state …rules and regulations."

73. GDC maintained a high degree of control over the premises leased by NECC.

74. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden and Glenn Chin compounded, tested, marketed and/or distributed MPA. MPA is a steroid that is used, *inter alia*, to treat neck and back pain. MPA is administered via spinal-area injection to patients with neck and back pain.

75. GDC and Gregory Conigliaro knew that NECC was compounding MPA at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

76. Until October 2012, NECC compounded MPA at its facility in Framingham, Massachusetts, and NECC sold MPA to healthcare providers in more than 20 states across the country.

77. On September 21, 2012, the Centers for Disease Control and Prevention (the "CDC") was notified by the Tennessee Department of Health of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.

78. On September 25, 2012, the CDC notified the FDA that it was working with the Tennessee Department of Health to investigate a cluster of meningitis cases at a single clinic (Saint Thomas Neurosurgical), which might be associated with product contamination.

79. On September 26, 2012, NECC recalled the following lots of methylprednisolone acetate (PF) 80mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

80. The FDA identified Saint Thomas Outpatient Neurosurgical Center in Nashville, Tennessee as one of the healthcare facilities that received vials of MPA that were part of the September 2012 recall. Saint Thomas Outpatient Neurosurgical Center is the location where Ella M. Redkevitch was injected with NECC's MPA.

81. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.

82. On October 6, 2012, NECC recalled all of its products. Health care professionals were told to stop using all NECC products immediately and to retain and secure all remaining products purchased from NECC until further notice from the FDA.

83. On or about October 8, 2012, Barry Cadden and Glenn Chin ceased their practice as pharmacists. Lisa Cadden also has ceased her practice.

84. On or about May 21, 2012, NECC sent to ARL two 5ml vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

85. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

86. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

87. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

88. On or about August 10, 2012, NECC sent one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

89. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were to be conducted in compliance with USP 71.

90. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL

Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

91. ARL was aware of the sterility risks posed by compounding pharmacies, specifically including the sterility risks posed by NECC's compounding practices.

92. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

93. In 2005, ARL's Chief Executive Officer, Thomas Kupiec, wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

94. In 2007, Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

95. In 2007, Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to be tested in relation to the number of articles in the batch" and a "14-day quarantine of the drug to await final test results[,]" Kupiec wrote in a 2007 published article that there should be "separate standards for compounding pharmacies and manufacturers."

96. ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

97. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded multiple microbiological isolates (bacteria and mold) within the Clean Room used for the production of MPA. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin knew or should have known of these findings. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to investigate and made no effort to identify those isolates. They failed to perform appropriate assessments for the products made in the Clean Room where the isolates were found, and failed to take any corrective actions with regards to the isolates that were found. In fact, NECC continued to compound MPA, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

B. DEENDANTS IGNORED SAFETY STANDARDS BY PRODUCING DRUGS IN A NON-COMPLIANT FACILITY

98. The Massachusetts Department of Public Health and FDA investigators identified serious deficiencies and significant violations at NECC that placed the

public's health and safety at risk. Each Agency has released reports on Defendants' longstanding widespread disregard for safety. The findings reveal conditions where bacteria and mold festered throughout the NECC facility and equipment.

99. On October 11, 2012, the FDA announced its findings showing the presence of a fungal contaminant in multiple sealed vials of MPA injection, made at NECC's facilities on GDC's property.

100. The Massachusetts Department of Public Health (DPH) investigators, in collaboration with investigators from the U.S. Food and Drug Administration (FDA), investigated NECC and released preliminary findings on October 23, 2012.

101. The DPH and FDA investigators identified serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk.

102. Some of the serious health and safety deficiencies noted by DPH were as follows:

- Visible black particulate matter was seen in several recalled sealed vials of methylprednisolone acetate from Lot *08102012@51.*
- Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation, within the sterile compounding area were not thoroughly cleaned pursuant to USP 979. Residual powder was visually observed within the hood during inspection. This contamination may subsequently lead to contamination of compounded medications.
- Condition of "Tacky" mats, which are used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry, violated the USP 797. Mats were visibly soiled with assorted debris.

- A leaking boiler adjacent to the requisite clean room created an environment susceptible to contaminant growth: "A pool of water was visually observed around the boiler and adjacent walls, creating an unsanitary condition; the culture results of this potential contaminant are still pending."

103. Surface samples from NECC's "clean" rooms revealed bacteria and mold, as did various equipment and parts of the facility. Air sampling showed "1 big mold" as far back as May 29, 2012. Air sampling throughout the facility revealed mold and bacteria.

104. FDA observed greenish yellow discoloration lining the interior surface of the viewing lens within the "Inside" autoclave used for steam sterilization of various components and equipment (e.g. vials of multiple sizes, stoppers, and spin bars) used in the formulation of sterile drug products. FDA further observed condensation along the interior surfaces of the "Outside" autoclave to collect in a pool at the base of the chamber.

105. The investigators also observed problems with NECC's ability to maintain its clean room, which is the enclosed space that is designed and maintained to have a controlled environment with low levels of airborne particles and surface contamination.

106. A used mattress processing facility, also owned by the Conigliaro family, abuts and operates under the same roof as NECC's facility. As FDA noted in its inspection, "The firm is abutted to the rear and along the left parking area by a recycling facility that handles such materials as mattresses and plastics. On 10/02/2012, the area was observed to include large equipment (e.g. excavators and freight trucks) producing

airborne particulates (e.g. dust). Rooftop units serving the firm's HVAC system were estimated to be located approximately 100 feet from the recycling facility."

107. FDA observed what appeared to be white filamentous substances covering the HVAC return located behind the autoclave used for steam sterilization located in the firm's Middle Room (ISO 7). FDA further observed greenish residue covering the surface of the ceiling exposed to the filter above, within Weigh Station 3 Hood located in the firm's ISO 6 Clean Room. The firm uses Weigh Station Hoods to weigh active ingredients and other raw materials utilized in the formulation of sterile drug preparations.

108. MSM and/or MSMSW marketed and Ameridose and/or distributed the products compounded in such deplorable conditions.

C. DEFENDANTS DISREGARDED PRIOR COMPLAINTS AND INSPECTIONS BY CONTINUING IMPERMISSIBLE CONDUCT AND IGNORING SAFETY RISKS

109. Defendants effectively ignored dozens of complaints from as early as April 1999. In 2002, two patients suffered an adverse effect after taking an NECC compounded steroid used to treat joint pain and arthritis. One victim subsequently died. FDA notified the state pharmacy board in October 2002 about an incident involving a drug the company had produced, methylprednisolone acetate, which is the same steroid that caused the current outbreak.

110. In 2004, an inspector report revealed that a toxin had been found in an NECC drug and that the company could not produce various records about the drug, including test results on its sterility. NECC and other Defendants failed to meet accepted standards that year for making the same steroid.

111. A 2006 letter to NECC from Pharmacy Support Inc., an outside evaluation firm, observed that the company continued to have significant gaps in its sterile compounding operation. That same year FDA issued warning letters to NECC.

112. NECC and other Defendants solicited out-of-state prescriptions for office use and used unapproved forms. NECC and other Defendants were aware of complaints regarding this practice and its improper promotional material and methods, but disregarded them.

D. ELLA M. REDKEVITCH'S EXPOSURE TO THIS TOXIN

113. In 2012, the NECC related Defendants caused numerous vials of methylprednisolone acetate contaminated with fungi and other contaminants to be shipped to Saint Thomas Outpatient Neurosurgical Center in Nashville, Tennessee. Upon information and belief, Ameridose distributed these vials to Saint Thomas Outpatient Neurosurgical Center on behalf of NECC.

114. Ella M. Redkevitch received epidural steroid injections on or about August 27, 2012, and September 17, 2012. She received these injections at Saint Thomas Outpatient Neurosurgical Center in Nashville, Tennessee.

115. Unknown to Ella M. Redkevitch, one or more of the injections she received came from contaminated lots of MPA purchased from NECC. The contaminated lots were subsequently recalled by NECC.

116. Ella M. Redkevitch contracted fungal meningitis, severe arachnoiditis, and had an epidural abscess.

117. Ella M. Redkevitch was hospitalized from November 16, 2012 through January 3, 2013.

118. She remained on anti-fungal medications until May 8, 2013.

119. As a direct and proximate result of the negligence of the Defendants, Ella K. Redkevitch contracted a serious fungal infection and became very ill. She continues to suffer from the effects of the fungal infection and its treatment.

COUNT I

NEGLIGENCE

(Against All NECC Related Defendants)

120. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein, and further allege:

121. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC Related Defendants owed a duty to Ms. Redkevitch to exercise due care in providing a safe and quality product to her.

122. Without limiting this general allegation of negligence, these Defendants were further negligent in the following ways:

a. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Ella M. Redkevitch a duty to provide methylprednisolone acetate that was safe and free of contamination.

b. ARL owed Ella M. Redkevitch a duty to properly conduct tests to insure that the methylprednisolone acetate was safe and free of contamination.

123. Defendants breached those duties and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to Ella M. Redkevitch. The Defendants, by and through its supervisors, staff and agents engaged in designing, compounding, sales, testing, marketing and distributing MPA in a negligent manner.

124. Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, test, and distribute MPA so that it would not be contaminated with a fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; and by allowing contaminated and unsafe medications compounded to reach the stream of commerce for use by Ella M. Redkevitch.

125. Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin breached the duties owed to Ella M. Redkevitch by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.

126. The negligence of these Defendants was a proximate cause of Ella M. Redkevitch's injuries.

COUNT II

NEGLIGENCE PER SE

(Against All NECC Related Defendants)

127. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein, and further allege:

128. Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Ella M. Redkevitch a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

129. Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin breached the duties owed to Ella M. Redkevitch by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

130. Defendants also violated Massachusetts' laws and its pharmacy licensing obligations.

131. As a direct and a proximate result of the negligence of the Defendants, Ms. Redkevitch sustained injuries.

COUNT III

NEGLIGENT SUPERVISION

(Against All NECC Related Defendants)

132. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein, and further allege:

133. Defendants Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin had an obligation and duty to exercise due care, to investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to Ella M. Redkevitch and others who received the compounded medications.

134. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Without limiting the above allegations, these Defendants were further negligent in the following ways:

a. failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.

b. failed to monitor and supervise the testing of the compounded medications.

c. negligent in hiring, training, and supervising their employees.

135. The Defendants knew, or should have known, that the employee or agent did not follow proper procedures and knew or should have known of the risks created by failing to do so.

136. As a direct and a proximate result of the aforementioned actions of the Defendants, Ms. Redkevitch sustained serious injuries.

COUNT IV

PUBLIC NUISANCE

(Against All NECC Related Defendants)

137. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein, further allege:

138. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

139. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

140. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

141. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.

142. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.

143. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

144. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC caused Ms. Redkevitch's injury.

145. As a direct and a proximate result of the above referenced acts and omissions of the Defendants, Ms. Redkevitch suffered serious injuries.

COUNT V

PRODUCT LIABILITY CLAIMS

(Against Saint Thomas Neurosurgical, St. Thomas Hospital, Saint Thomas, and Ascension Health)

146. The MPA injected into Ella M. Redkevitch's spine was compounded by NECC.

147. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts, In re: New England Compounding Pharmacy, Inc., Case No. 12-19882-HJB.

148. Pursuant to 11 U.S.C. § 362(a)(1), certain actions against NECC are stayed following its bankruptcy petition.

149. Claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).

150. NECC has ceased operations.

151. NECC is unable to pay its debts as they fall due.

152. NECC is unable to pay its debts in the ordinary course of its business.

153. NECC's liabilities exceed its assets.

154. NECC is insolvent.

155. On July 24, 2013, The United States Bankruptcy Court for the District of Massachusetts in In re: New England Compounding Pharmacy, Inc., Case No. 12-

19882-HJB, ordered that with respect to certain claims, NECC is presently insolvent and has been insolvent at all times since the petition date.

156. Saint Thomas Neurosurgical procured the MPA injected into Ella M. Redkevitch's spine from NECC.

157. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same condition at the time that Saint Thomas Neurosurgical injected it into Ella M. Redkevitch's spine.

158. Saint Thomas Neurosurgical charged Ella M. Redkevitch for epidural steroid injections administered to Ella M. Redkevitch.

159. Saint Thomas Neurosurgical acted as a seller or distributor of MPA compounded by NECC when it sold and administered epidural steroid injections to patients, including Ella M. Redkevitch.

160. Saint Thomas Neurosurgical was engaged in the business of selling MPA compounded by NECC.

161. Accordingly, Saint Thomas Neurosurgical is a "seller" as defined by Tenn. Code Ann. § 29-28-102(7).

162. Tenn. Code Ann. § 29-28-106(4) and (5) authorizes Plaintiffs to prosecute product liability claims against Saint Thomas Neurosurgical as the seller of the MPA injected into Ella M. Redkevitch's spine because the compounder of the product, NECC, cannot be served with process and has been judicially declared insolvent.

163. The MPA that Saint Thomas Neurosurgical injected into Ella M. Redkevitch's spine was unreasonably dangerous and defective at the time it left its control because it was contaminated with lethal pathogens.

164. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

165. The MPA sold and distributed by Saint Thomas Neurosurgical was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Saint Thomas Neurosurgical breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313,47-2-314, and 47-2-315, including their warranty of fitness for a particular purpose.

166. Saint Thomas Neurosurgical is strictly liable for the serious injuries, harms, and losses caused by the unreasonably dangerous and defective steroids injected into Ella M. Redkevitch.

167. Saint Thomas Neurosurgical is the actual, ostensible, and apparent agent of St. Thomas Hospital. Therefore, St. Thomas Hospital is liable for its agent, Saint Thomas Neurosurgical.

168. Saint Thomas Neurosurgical is the actual, ostensible, and apparent agent of Saint Thomas.[1] Therefore, Saint Thomas is liable for its agent, Saint Thomas Neurosurgical.

169. The "Ascension Health" Defendants owned, operated, managed and/or simply did business, in part, as Saint Thomas Health, and/or Saint Thomas Network, and/or Saint Thomas West Hospital, formerly known as St. Thomas Hospital. Per its website, Ascension Health lists Saint Thomas Health (http://www.sths.com) under Ascension Health's "Hospitals and Facilities.

170. On Ascension Health's IRS Form 990, Schedule R, Part I, Ascension Health is listed as the "direct controlling entity" of Saint Thomas Health.

171. On Ascension Health's IRS Form 990, Schedule R, Part III "Identification of Related Organizations Taxable as a Partnership," Saint Thomas Outpatient Neurosurgical Center, LLC is among the entities listed.

172. Through its relationship with Saint Thomas Health, and/or Saint Thomas Network, and/or Saint Thomas West Hospital, formerly known as St. Thomas Hospital, and Saint Thomas Outpatient Neurosurgical Center, LLC, the "Ascension Health" Defendants are liable for the liability of Saint Thomas Health, and/or Saint Thomas Network, and/or Saint Thomas West Hospital, formerly known as St. Thomas Hospital and/or Saint Thomas Outpatient Neurosurgical Center, LLC. To the extent that the

[1] As noted in paragraph 28 above, Defendants Saint Thomas Network and Saint Thomas Health are collectively referred to as "Saint Thomas."

Ascension Health Defendants may claim that a corporate veil may exist to preclude liability, justice and equity require that any such alleged veil be pierced.

173. Out of an abundance of caution, neither this claim, nor any other claim or count asserted in this action, is meant to allege a claim arising under or otherwise covered by the Tennessee Medical Malpractice Act, T.C.A. section 29-26-101, *et. seq.* Plaintiffs have served notice letters as required by the TMMA, but sixty days have not yet passed since service of those letters. Plaintiffs file this action to preserve their products liability action, and will either file a separate lawsuit to be joined with this one, or amend this complaint to add, in the alternative, claims under the TMMA at the appropriate time.

DAMAGES

174. As a direct and proximate result of the Defendants' wrongful conduct, Plaintiffs have suffered and continue to suffer harm, injury, and damages. The Plaintiff Ella M. Redkevitch's damages include, but are not limited to: Severe pain and suffering, mental anguish, disability, emotional distress, past and future medical care and treatment, increased living and support expenses, loss of enjoyment of life, medical expenses, both past and future.

175. The Plaintiff Neil Z. Redkevitch also has suffered as a direct result of the wrongful conduct of the Defendants. He has watched his wife suffer. He has suffered a

loss of consortium and has endured much mental anguish. He has incurred, and will continue to incur, medical expenses and increased living and support expenses.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendants as follows:

176. Ella M. Redkevitch and Neil Z. Redkevitch respectfully demand that the Defendants be held accountable for all damages and demand of the Defendants as compensatory damages the sum of EIGHT MILLION AND NO/100 ($8,000,000) DOLLARS.

177. Plaintiffs demand a judgment for punitive damages in an amount to be determined by the trier of fact.

178. Plaintiffs demand a trial by jury.

179. Plaintiffs respectfully pray for the costs of court, pre-judgment and post-judgment interest, and all other costs allowed by law.

180. Plaintiffs pray for such further relief as the Court may deem just and proper.

Respectfully submitted,

KINNARD, CLAYTON & BEVERIDGE

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